October 8, 2004

Arthur L. Williams
Director
Louisville Metro Air Pollution Control District
850 Barret Avenue
Louisville, KY 40204-1745

Deliver via email

Re: Informal Public Comments Concerning the Proposed Strategic Toxic Air Reduction Program, September 16, 2004

Dear Mr. Williams:

Arkema, Inc. (formerly ATOFINA Chemicals, Inc). is pleased to submit informal comments on the Louisville Metro Air Pollution Control District (APCD) proposed Strategic Toxic Air Reduction (STAR) program, published on September 16, 2004. Arkema operates a chemical manufacturing facility that will be regulated by this regulation.

Arkema Chemicals fully supports the comments of Greater Louisville, Inc., and incorporates those comments into this submittal by reference.

Please contact me with any questions. Arkema looks forward to working with APCD during the formal comment period to refine these comments and optimize the STAR program. Thank you.

Sincerely,

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BEFORE THE LOUISVILLE METRO AIR POLLUTION CONTROL DISTRICT

INFORMAL COMMENTS OF ARKEMA INC.

ON

APCD'S PROPOSED RULE ESTABLISHING THE STRATEGIC TOXIC AIR REDUCTION PROGRAM

Proposal Date September 16, 2004

October 8, 2004

Introduction

Arkema, Inc. (Arkema), formerly ATOFINA Chemicals, Inc., hereby submits comments on the Louisville Metro Air Pollution Control District's ("APCD") proposed rule establishing the Strategic Toxic Air Reduction (STAR) program dated September 16, 2004. APCD's proposed STAR Program would directly impact Arkema, as operator of two hazardous waste combustor units. Arkema submits the following comments for consideration by APCD, and also incorporates by reference into these comments those submitted by the Greater Louisville, Inc.

Arkema describes below a number of specific issues that should be further clarified, modified, or deleted by APCD from the final regulation (STAR Program) to insure that if the APCD proceeds with this regulation, the final rule is both clear in its intent and also reasonable in its approach to regulate affected industry. Among other issues, Arkema is concerned about how the proposed STAR Program impacts sources that are in the process of obtaining Federally Enforceable District Origin Operating Permits (FEDOOP), such as the Arkema facility.

Specific Comments

1. APCD Must Take Advantage of Opportunities to Harmonize the STAR Program with State and Federal Obligations.

The APCD's proposal does not contain any language to "harmonize" it's provisions with existing air toxics obligations that are required by existing Commonwealth of Kentucky and United States requirements. Any final STAR program must ensure seamless compliance with requirements that could conflict if not developed carefully. If a provision is not available to adjust the STAR Program to KYDEP and/or USEPA requirements, industry could be faced with trying to comply with two conflicting rules. Additionally, if the STAR Program does not have a provision to adapt to KYDEP and/or USEPA provisions, the rule could be found to be in conflict with others rules and thereby be voided.

a. Federal Obligations. Many sources in Jefferson County, including Arkema, are currently major sources of Hazardous Air Pollutants (HAP), as defined in Section 112(b) of the Clean Air Act. Those major sources of HAP, if they do not reduce their potential to emit HAP below major source thresholds, will be subject to the EPA's Maximum Achievable Control Technology (MACT) program. Sources in the MACT program are further subject to the residual risk standards of Section 112(f) of the Clean Air Act. The residual risk standards are designed to accomplish the same goals as STAR, the assurance of an ample margin of safety (AMOS) for citizens residing near major sources of HAP. EPA is currently performing extensive evaluations for residual risk rules that will impact facilities within Jefferson County. However, the proposed STAR regulation package does not address conformity issues between two programs with the same goal. Arkema recommends that APCD exempt any source subject to any Section 112(f) standard from the STAR program, or designate that facilities subject to EPA residual risk standards are automatically in compliance with STAR.

EPA also requires MACT facilities to comply with startup, shutdown, and malfunction plans (SSM) for all process units regulated by the MACT program. The proposed STAR regulations are not harmonized to ensure consistency between the APCD and EPA SSM requirements for MACT units. APCD should develop consistent SSM regulations to ensure seamless compliance.

b. Commonwealth Obligations. Under Kentucky Law, APCD is required to ensure that air pollution regulations within Jefferson County are at least as stringent as those regulations governing the remainder of the Commonwealth. Arkema is currently participating in a statewide task force sponsored by the Kentucky Department of Environmental Protection (DEP) that is currently evaluation air toxics regulatory options. Once the DEP air toxics rules that will likely emerge from this effort are finalized, APCD is required to review the new regulations and ensure that the APCD regulations are at least as stringent as the DEP regulations that apply to the remainder of Kentucky. Arkema requests that APCD ensure full equivalence and consistency between APCD's efforts and DEP's efforts before the STAR program compliance date. Otherwise, APCD takes the risk of forcing Jefferson County to become subject to a program that may very likely be required to change immediately before, or shortly after, the compliance date. Multiple rulemaking is an undue burden on the Jefferson County regulated industry, and APCD should ensure that STAR implementation would not be complicated by DEP/USEPA requirements that could require substantive changes mid-stream.

2. APCD Must Not Develop Site-Wide Air Toxics Regulations Based on Construction Permitting Regulations.

a. The Michigan Model is Inappropriate. APCD obviously used the Michigan DEQ regulatory system as a model by which to develop the proposed STAR air toxics regulations. This use of Michigan's construction permitting model is inappropriate and should be abandoned. The Michigan regulations (Michigan R336.1220-1230 series) are used to regulate new or modified sources of air pollution, and are only applied on an incremental basis for those process units subject to the modification. In no instance does Michigan regulate site-wide air toxics emissions. However, several states, including South Carolina, Louisiana, and others, have existing site-wide air toxics regulations that would serve as a much better regulatory model than the existing Michigan rules. The Michigan regulations have been seen by local industry as rigid and unworkable for several reasons. Arkema has had difficulty navigating the toxics limit setting process duplicated in this rule, primarily due to the lack of due process in the limit setting process and Michigan's requirement that the facility petitioning for a limit decision produce original toxicological studies used to set the limit. Such studies are not normally available to competitors setting up to manufacture a competing product, and the toxicology community considers repeating valid existing animal study work unethical to replicate. Thus, the unjustified 0.04 microgram per cubic meter default value is used far too frequently, and in inappropriate circumstances. Michigan has had difficulty communicating what cost-effective targets are

appropriate under their regulations. Review times for the Michigan air toxics process have added weeks to months to the construction permitting review process. Arkema is not aware of APCD employing adequate staff levels required to devote the amount of extra time required to execute a program the magnitude of the Michigan program.

The South Carolina regulations (South Carolina Regulation 61-62.5, Standard 8) include several features that are very useful and helpful for APCD, the Jefferson County community, and industry. First, these rules include air toxics limits for the regulated compounds directly in the regulation. This feature ensures that air toxics values derived from suspect sources, such as the contested 1,3-butadiene values with EPA's IRIS database, are subject to review and comment before becoming applicable. This allows APCD, the Jefferson County community, and industry assurance that the appropriate protections are available for the community, and allows a legally defensible mechanism for the community to challenge any regulatory limits not deemed as reasonably protective. If APCD devotes the appropriate resources to the standard-setting process early during the STAR implementation, this process may not need to be used often, and should not cause significant delays in permit issuance. Arkema requests that APCD address this potential resource issue in any final STAR regulation and ensure that APCD staff includes an appropriate number of toxicology and air toxics experts to operate the program efficiently.

b. De Minimis Levels. South Carolina provides for a de minimis level, below which the South Carolina Department of Health and Environmental Conservation (DEHC) needs not consider trivial sources of air toxics (Appendix D of the July 2001 "Air Toxics Modeling Guidelines" provides a detailed explanation of this process). Michigan also provides a mass-based air toxics de minimis under R336.1290 (200 lb/month non-carcinogens).

c. Presumptive Limits. South Carolina does not require an arbitrary presumptive 0.04 microgram per cubic meter fenceline limit that cannot be supported by the toxicity literature.

d. Experience With Michigan's Program. Arkema's experience with the Michigan program has historically been problematic. Michigan DEQ has not proven to be accepting of published literature to justify regulatory limits under the Michigan air toxics program. Michigan DEQ's decisions concerning air toxics limits are only publicly reviewable during the comment period for the single construction permit action for which the limit was developed. While this procedure is possibly protective for any interested citizens within the immediate neighborhood of the facility subject to the permitting action – but only if the citizen is aware of the individual permit action where the limit is being adopted – the community at large has no meaningful way to provide input on toxics levels in a structured manner in Michigan, as they can in South Carolina and other jurisdictions.

e. Best Available Technology Demonstrations. The Michigan program is only used to evaluate construction permitting activities. The Toxics-Best Available Technology (T-BAT) program only evaluates control options for new or modified emissions sources. As such, the Michigan program has no provisions for evaluating existing source control standards. In most of EPA's Maximum Achievable Control Technology (MACT) standards at 40 CFR 63, EPA recognizes the fundamental differences between existing source control economic and technical feasibility and new source control economic and technical feasibility. EPA often sets different control standards for new versus existing emission sources. Since the Michigan program has never had to answer this question, APCD must prepare a detailed regulatory and feasibility analysis to describe how they will review what T-BAT might be for new sources, and how this determination would differ from existing source controls. These determinations must be described in any final STAR regulation.

3. APCD Should Provide a Change Management Procedure for Air Toxics Levels.

In the proposed STAR program, APCD does not provide any change management program when one or more fenceline limit concentrations must be changed. As these changes are usually a result of new science available from the peer review process or from an agency's publication of new air toxics data, a facility could become at risk of violating STAR by no action of their own with no notice. First, Arkema proposes that the APCD conduct a notice-and-comment rulemaking on a periodic schedule, every six months for instance, where the public is given a structured opportunity to comment on all proposed air toxics limits changes. Arkema also proposes that APCD be allowed to use a "proposed" limit for a specific construction permit action regulated under the STAR program, but that the facility be allowed to adjust any new limits for any changes in the public review process during the limit finalization process. This proposed limit would be posted not less frequently than every month to the APCD web site to allow the public to prepare for the upcoming comment period.

Second, Arkema recommends that APCD allow a facility a fixed period of time to adjust to a new air toxics limit where the new limit could potentially increase stringency of the STAR program at a facility. This would include a three-step process. The first step would be a mandatory air toxics review that would be due within six months of the new air toxics value being finalized by APCD. The second step would be a facility proposal of controls to meet the new fenceline limits, or an evaluation of an appropriate ample margin of safety, as discussed later in these comments, to protect public health. This evaluation would be due within 90 days after any APCD finding that a facility's risks could potentially indicate that a new control review might be necessary. The third step would include 18 to 24 months to implement any required controls that are agreed upon between the facility and APCD. APCD would also include an application shield to ensure that facilities completing the reevaluation program would not be subject

to enforcement while the process continues. Such an application shield would also be in force during any agency review periods and equipment installation periods, and would end when the facility certifies normal operation under the new compliance plan. Only a final agency action finding that the facility has not completed its obligations under the STAR program would initiate enforcement. Such a structured evaluation, risk assessment, and implementation period ensures adequate public protection, proper APCD oversight, and technical feasibility for the facility.

4. <u>APCD Must Reevaluate The Interaction Between Existing Emergency Regulations and the Affirmative Defense Portions of the STAR Proposal.</u>

APCD proposes in the STAR rulemaking package to adopt a version of the September 20, 1999 EPA memorandum "State Implementation Plans: Policy Regarding Excess Emissions from Malfunctions, Startups, and Shutdowns." Arkema is concerned that, by removing the emergency provisions of the existing standard, that APCD's proposal is not consistent with the affirmative defense concept in the EPA memo. APCD's existing emergency conditions meet the intent of EPA's memo without further rulemaking. For events that do not meet the APCD's legacy emergency definition, the procedures outlined in the EPA memo may be appropriate. Arkema requests that APCD reconsider how the affirmative defense, the existing emergency provisions interact in any final STAR package. Also, emergency actions are not indicative of long-term risk, and therefore should be excluded from this regulation.

Arkema is concerned about the one-hour notification requirement, especially since APCD does not propose to operate a 24-hour response center to manage emergency emissions situations. Jefferson County operates an existing emergency notification system (911) that are already set up to log emergency events where first responders are required to take action to manage potential excess emissions events. Arkema requests that APCD continue the existing system where APCD can access 911 records for facilities subject to the STAR program, and that the one-hour notification be waived for any emergency event where 911 was notified of the event. A two business day follow-up report is adequate to serve APCD's needs when APCD will not be equipped to respond to an excess emissions event prior to the next business day.

EPA has already addressed the magnitude of releases that must be reported to the National Response Center in the Reportable Quantity regulations under SARA. In the recent Texas release reporting regulations, Arkema facilities in Texas are only required to report excess emission events when an RQ value is exceeded. This provision allows the local agency (Texas Commission on Environmental Quality or TCEQ) to concentrate on those releases that EPA and TCEQ consider significant. Arkema recommends that APCD only require affirmative defense reporting when emissions from the event exceed a permit limit by not less than the RQ amount.

APCD proposes that any deviations under the STAR program are automatically considered violations of APCD regulations. However, due to the far-reaching nature of the STAR program, this blanket claim cannot be made. Congress recognized in the Clean Air Act that credible evidence might be used as an appropriate indicator of environmental performance. While agencies throughout the United States have used credible evidence in enforcement actions, facilities, including those owned and operated by Arkema, have successfully used credible evidence to identify why a deviation from a monitoring limit that might be required under a Title V permit may not represent a violation of any applicable requirement. APCD must allow the EPA's credible evidence system to be used in the STAR program not only as an enforcement trigger, but also as an enforcement defense.

5. <u>APCD Should Clarify FEDOOP Status For Facilities Where FEDOOP Applications Are Pending.</u>

The Arkema Louisville facility is currently in the process of obtaining a APCD Federally Enforceable District-Origin Operating Permit (FEDOOP). The applicability language in the proposed STAR program should recognize that facilities in the FEDOOP application process are undergoing process changes to reduce emissions, or have recently completed emission reduction projects. These facilities should be allowed to join facilities that already operate under FEDOOP permits until the final compliance date for Title V facilities. APCD should clarify that existing pending FEDOOP facilities are grouped with the existing FEDOOP facilities, unless the FEDOOP permitting action is denied by a final agency action or the required emission reduction requirements are not completed before the expiration of the underlying construction permit obtained to complete the emission reduction project(s). APCD should further clarify that the FEDOOP fee structure applies to facilities that are awaiting final approval of their FEDOOP applications.

6. <u>APCD Must Provide Reasonably Cost-Effective Options for Air Toxics Control Requirements.</u>

APCD has proposed a best-available technology cost-effectiveness evaluation to ensure that any and all cost-effective controls are applied to reduce air toxics risks. The underlying problem with such rules is the lack of guidance that many agencies provide to facilities when evaluating cost-effectiveness for a specific application. EPA has addressed this issue in the Best Available Control Technology area, and is now in the process of addressing this issue in the residual risk program. Agencies usually set target cost-effectiveness targets for organic and inorganic control devices. Arkema recommends that APCD set organic and inorganic cost targets to ensure clarity for the public when a control technology review is required. These targets can be adjusted during periodic rulemakings that

are otherwise required to update air toxics regulatory values and fee structures to ensure that APCD is adequately funding the Clean Air Act regulatory program.

7. <u>APCD Must Develop a Reasonable Ample Margin of Safety Provision for Setting Air Toxics Limits.</u>

APCD proposes that a cancer risk of $1.0 * 10^{-6}$ is appropriate at the physical fence line under the proposed STAR program. In theory and in application, APCD's approach is problematic and should be revamped.

a. <u>Receptor Locations.</u> In general, APCD assumes that the most appropriate place to regulate risks is at the physical fenceline. In jurisdictions that do not regulate carcinogen risk separately from non-carcinogen risk, such as South Carolina, such a conservative assumption is used to simplify the air toxics review process. In the upcoming EPA residual risk program, EPA is using census track centroids to evaluate carcinogen risk. Arkema recommends EPA's approach as one option to evaluate risks at locations where risks actually occur, not at a theoretical location where no actual person will ever live, work, or occupy that location for any significant period of time. A second approach that would also work is to require the facility to identify the nearest residential-use location (school, church, home) and incorporate those nearby locations into the receptor grid.

b. <u>Allowances for Industrial Use Corridors and Transportation Corridors.</u> One facet of the Michigan program that APCD neglected to incorporate into the STAR proposal was the authority to increase any risk-based limit by a factor of ten at any location that was not likely to become a long-term receptor. In Arkema's Michigan experience, known industrial properties, roads, railroad track locations, and utility easements are allowed a factor of ten risk adjustment to account for the absence of human receptors in these locations. Arkema recommends that APCD adopt only this portion of the Michigan air toxics program.

In addition, the Texas air toxics program includes a provision that adjacent industrial sites that operate in tandem may petition the agency to designate the combined location as a single site for air toxics purposes. Arkema has used this provision to evaluate air toxics compliance where Arkema's operations are directly tied into another company's operations. Arkema operates the Louisville facility under similar conditions, where a symbiotic relationship exists between Arkema and an adjacent facility.

c. <u>Modeling Process.</u> APCD included a detailed, but incomplete, description of issues that must be addressed during any dispersion modeling demonstration. APCD also included a detailed modeling protocol, including descriptions of exact dispersion models, which must be used to demonstrate compliance with the air toxics regulations. Issues that have been excluded from the STAR proposal include the use of volume sources to model leak detection and repair related emissions, designation of the discharge direction, designation of meteorological

data used in the modeling, use of local grids with UTM benchmark locations, and model version updates and replacements. The number of issues that must be considered in a modeling evaluation, and the rate of change of these parameters, does not allow for timely and reasonable rulemaking. Arkema recommends that APCD adopt by reference the existing EPA "Guidelines for Air Dispersion Models" in 40 CFR 51 Appendix W instead of codifying portions of this document in the STAR proposal in lieu of detailed descriptions of the modeling system in the proposal. In addition, APCD must provide some guidance concerning the use of standardized meteorological data when onsite meteorological data is used for a modeling demonstration. Arkema recommends that APCD post appropriate ISCST and/or AERMOD meteorological data on it's web site.

d. Risk Levels and Hazard Indices. APCD has proposed a very strict toxics limit of a cancer risk of $1 * 10^{-6}$ and a hazard index (HI) of between 0.1 and 10. APCD must justify why these limits were set, and provide a technical and economic justification of each value presented for Title V and/or FEDOOP facilities. These restrictive risk levels are not consistent with what EPA is now determining constitutes an Ample Margin of Safety (AMOS) under the existing 40 CFR 61 NESHAP standards or the recent 40 CFR 63 residual risk standards. APCD's assumption that their restrictive toxics limits has not been justified. Arkema requests that APCD conduct an analysis to demonstrate what AMOS levels are appropriate, given EPA's definitions in Section 112(f) of the Clean Air Act that require that AMOS be set between $1 * 10^{-4}$ and $1 * 10^{-6}$. Arkema also recommends that APCD consult with EPA concerning where AMOS would be set for non-carcinogens, especially since EPA is currently discussing utilizing hazard indices between 1 and 20. An appropriate residual risk rule to use as a model would be the Hazardous Organic NESHAP, now being developed by EPA for the chemical industry. Several companies operating in Jefferson County operate facilities that will become subject to this standard in the next few months.

8. APCD Has Not Justified Unprecedented Increases in Leak Detection and Repair Program Stringency.

APCD has proposed draconian increases in stringency to the required Leak Detection and Repair programs that do not exist in any jurisdiction where Arkema operates. Arkema currently operates under state-origin LDAR programs in Texas and Michigan and Federal LDAR requirements (40 CFR 63 Subpart H). APCD does not justify why monitoring of equipment that has not traditionally been considered significant sources of equipment leaks (such as sight glasses) should be monitored under any LDAR program. Arkema recommends that APCD justify why such a drastic extension of the LDAR program is warranted. APCD should allow equivalence for any source complying with LDAR programs equivalent to EPA's HON (40 CFR 63 Subpart H), standard standards (40 CFR 63 Subpart UU), Consolidated Air Rule (40 CFR 65 Subpart F), and RCRA (40 CFR 264/265 Subpart BB) LDAR programs. Arkema currently operates a Subpart H equivalent

program at the Louisville facility that was initiated to reduce emissions potentials to below major source levels. This emission reduction effort should be rewarded in any final STAR program as a compliant program.

9. <u>APCD Should Provide Flexibility To Adjust the STAR Program to Changes in EPA's HAP List</u>.

EPA lists a number of constituents in the various categories of regulated air toxics in the proposed STAR program. Table 3 includes all HAPs that were not listed in the prior lists. Arkema recommends that APCD rely on EPA's HAP list at Section 112(b) of the Clean Air Act. Reliance on EPA's list will ensure that APCD will not have to adjust the STAR regulations when EPA changes the HAP list. In addition, Arkema supports APCD's concept that constituents not identified as a risk contributor in Jefferson County or on the Federal HAP list should not be presumptively placed on any of the STAR program air toxics lists.

10. <u>APCD's Assumptions Used To Justify the STAR Program are Flawed</u>.

APCD presumes that the total carcinogenic risk that the Jefferson County community is subject to is derived from large fixed manufacturing facilities. However, the 1996 EPA National Air Toxics Assessment (get link here) indicated that, on a national average, approximately 90% of the airborne risk borne by Americans does not originate at the facilities that are targeted by this proposed rulemaking. The predominant source of risk is the on-road and off-road mobile source categories, such as cars, trucks, construction equipment, and marine traffic. APCD must conduct a risk assessment that includes the contributions from air emission sources that are not regulated in the proposed STAR program that cause carcinogenic risks within the Jefferson County community, including the timely reinstatement of the vehicle emissions testing program recently cancelled by APCD. Removing restrictions on the largest source of carcinogenic risk (other than tobacco use) within a community while adding restrictions to a smaller risk contributor is counterproductive and very costly to the community, especially if one or more STAR facilities are forced to reduce employment or shut down to comply with this proposed regulatory program.

11. <u>APCD Must Reassess The Procedure for Determining Which Constituents Are Inhalation Carcinogens</u>.

Arkema is concerned that APCD is using a very inaccurate procedure to determine which constituents should be listed as carcinogens. Arkema is also concerned that APCD is not following the procedures in the proposed STAR program to populate the carcinogen list. Arkema utilizes ethyl acrylate in it's processes in the Louisville plant. Recent science indicates that ethyl acrylate is

not an inhalation carcinogen. Below is a description of APCD's proposed carcinogen determination method, and an explanation of why ethyl acrylate does not meet APCD's carcinogen definition using APCD's logic. APCD must review each chemical that may be named as a carcinogen, and determine which, if any, of the identified compounds meet APCD's own definition. APCD's proposed regulatory language is *italicized*, reference material is in Arial font, and Arkema's comments are in standard Times New Roman font.

SECTION 2 Determination that a Toxic Air Contaminant is a Carcinogen

2.1 A toxic air contaminant (TAC) shall be determined to be a carcinogen if any of the following provisions is met:

2.1.1 A carcinogenic unit risk estimate, or alternatively, a concentration representative of a specified level of additional lifetime cancer risk, for the TAC is included in any of the information sources identified in section 3.3,

2.1.2 The TAC is listed as either 'known to be a human carcinogen' or 'Reasonably anticipated to be a human carcinogen' in the most recent Report on Carcinogens published by the National Toxicology Program pursuant to Section 301(b)(4) of the Public Health Service Act as Amended by Section 262, PL 95-622, available on the Internet at \\http://ehp.niehs.nih.gov.roc, or

Ethyl acrylate (EA) does not appear on the 10th NTP Report on Carcinogens (ROC) issued December 2002. EA was delisted in the 9th ROC (2000). The NIEHS Fact Sheet provides the following summary to explain the change:

Ethyl acrylate - Ethyl acrylate, a substance used in making latex paints and textiles, which had been listed since 1989 as "*reasonably anticipated to be a human carcinogen*," was also delisted. The Basic Acrylic Monomer Manufacturers, Inc. (BAMM) had nominated ethyl acrylate for delisting, which led to a new review of the carcinogenicity data for ethyl acrylate. The review found that tumors induced in animal studies were seen only when the chemical was given by an oral route at high concentrations, resulting in persistent and severe gastric tissue injury. Because significant chronic human oral exposure to high concentrations of ethyl acrylate is unlikely, it was concluded that ethyl acrylate should not be considered "reasonably anticipated to be a human carcinogen."

2.1.3 The District determines that the TAC should be considered to be a carcinogen because there is sufficient, credible information that any of the following criteria is met:

2.1.3.1 Known to be a human carcinogen: There is sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between exposure to the agent, substance, or mixture and human cancer,

This condition is not met for ethyl acrylate.

2.1.3.2 Reasonably anticipated to be a human carcinogen:

2.1.3.2.1 There is limited evidence of carcinogenicity from studies in humans, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded,

2.1.3.2.2 There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates there is an increased incidence of malignant or a combination of malignant and benign tumors: (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence,

site, or type of tumor, or age at onset, or
2.1.3.2.3There is less than sufficient evidence of carcinogenicity in humans or laboratory animals, however; the agent, substance, or mixture belongs to a well defined, structurally-related class of substances whose members are listed in the most recent Report on Carcinogens published by the National Toxicology Program as either a known to be human carcinogen or reasonably anticipated to be human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

These conditions are not met for ethyl acrylate.

2.2 In making a determination pursuant to section 2.1.3, the following provisions shall apply:

2.2.1 Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive subpopulations, genetic effects, and other data relating to mechanism of action or factors that may be unique to a given substance. This applies to both the 'known to be a human carcinogen' and the 'reasonably anticipated to be a human carcinogen' categories, and

2.2.2 For an agent to be determined 'known to be a human carcinogen', evidence from studies of humans is required. This may include traditional cancer epidemiology studies, data from clinical studies, or data derived from the study of tissues from humans exposed to the substance in question and useful for evaluating whether a relevant cancer mechanism is operating in humans.

The petition to delist ethyl acrylate from the Report on Carcinogens was based on the following data and considerations.

1. Ethyl acrylate caused forestomach tumors in rats after dosing by oral gavage in corn oil. A series of subsequent mechanistic studies, most prominently those by NTP scientists, demonstrated that gavage dosing of ethyl acrylate produced localized inflammation and hyperplasia at the site of contact in the rodent forestomach. This response was reversible unless daily gavage dosing continued for six months, in which case the lesions progressed to tumors. The observed response was concentration rather than dose-dependent. No such toxicity or carcinogenicity was observed in the rodent glandular stomach, which received a comparable dose to that of the forestomach.

2. Chronic animal studies employing other routes of exposure, including inhalation, dermal and drinking water exposure, produced no increase in tumors and no toxic response other than slight irritation at the point of contact. Drinking water exposure involving the same daily dose used in the NTP chronic gavage study produced no carcinogenic or toxic response.

3. Extensive metabolic data demonstrate that ethyl acrylate is rapidly metabolized in the body into non-toxic metabolites. Any toxic effects of ethyl acrylate would therefore be expected to occur only at the point of contact. This is confirmed by the lack of any systemic toxicity in any of the numerous studies on ethyl acrylate.

4. While ethyl acrylate produces a positive response in certain types of *in vitro* genotoxicity assays (e.g., mouse lymphoma assay), it generally does not produce a

genotoxic response in *in vivo* studies. Recent studies demonstrate that the positive in vitro results occur only at concentrations associated with high levels of cytotoxicity.

5. Human ethyl acrylate exposures are almost exclusively via inhalation, with some potential for dermal exposure in occupational settings. Exposures are very low in both occupational and non-occupational settings. The strong, noxious odor of ethyl acrylate at very low concentrations (odor threshold of approx. 0.5 ppb) ensures that human exposure remains negligible. Human exposure levels therefore never approach the very high concentrations of ethyl acrylate needed to overwhelm the detoxification pathways even in the most sensitive rodent forestomach tissue.

   Similarly, regarding workplace exposures, the American Conference of Governmental Industrial Hygienists (ACGIH) has re-evaluated and reclassified ethyl acrylate from an A2, Suspected Human carcinogen rating (adopted in 1990) to an A4, Not Classifiable as a Human Carcinogen rating (adopted in 1996).

   During the formal comment period, Arkema will develop a regulatory analysis regarding the listing of butyl acrylate, another listed constituent that Arkema could potentially utilize in the Louisville plant operations.

Conclusion

Arkema reserves the right to supplement these comments during the formal comment period. Such a supplementary comment may further explain issues identified in this document or may raise additional issues that are not included in the informal comments. Arkema thanks APCD for the opportunity to comment on the proposed STAR Program and looks forward to their responses to our comments.